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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,639	10/24/2001	Cesar C. Carriazo	CARA/0013	1980

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EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/002,639

Applicant(s)

CARRIAZO, CESAR C.

Examiner

D Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/24/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5, 7, 9 and 10 are rejected under 35 U.S.C.102(b) as being anticipated by Hellenkamp (US 6,007,553). Hellenkamp discloses a surgical device for cutting the cornea (Fig. 4-10B) comprising a ring 32, a vacuum channel 37, and circular inferior and superior engaging surfaces each having a convex surface. The ring is made of stainless steel (Col. 6, lines 65-67). The surfaces of the ring may engage an "aspherical ocular globe-engaging surface," even if more suction is required to stabilize the eye. The ring is circular. With respect to claims 4 and 5, the inferior engaging surface defines a meridian having a radius and the superior engaging surface defines a median having a different radius. As illustrated in Figs. 2 and 4, the superior engaging surface has a non-circular plane section formed by a beveled wall. The plane section is formed by the entire top surface area of the ring 32. The device is capable of being used with an aspherical ocular globe.

Claims 1-6, 9-11, 13-15, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Silvestrini et al. (US 6,143,010). Silvestrini discloses an apparatus (Figs. 9-12) capable of securing an aspherical ocular globe comprising a ring 502 and 504 comprising an annular vacuum channel. The device comprises inferior and superior engaging surfaces 514 and 512, respectively. The aperture of the inferior engaging surface 504 is non-circular and specifically elliptical (Col. 8, lines 46-57). The inferior engaging surface defines a major radius and the superior engaging surface forms a minor radius, the two radii being different. A non-circular wall, a beveled wall, and a variable length wall form the non-circular plane section of the inferior engaging surface. The inferior and superior engaging surfaces are concave and mate with the ocular globe. The device is made of stainless steel or titanium (Col. 8, lines 13-16).

In addition, Silvestini discloses a kit to be used with a microkeratome comprising a plurality of rings, one of which is illustrated in Figs. 3-5, and another is illustrated in Figs. 9-11. Each of the rings has an annular vacuum channel, inferior and superior engaging surfaces, and differ in the inferior engagement surface shape. The limitations of the dependent claims are met as described in claim set 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of the appropriate paragraph of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 7 and 8 are rejected under 35 U.S.C. 103(c) as being unpatentable over Silvestrini in view of Kawesch (US 6,350,272). Silvestrini discloses the limitations of claim 1, but fails to disclose a superior engaging surface having a non-circular plane section and having oval shape. The interior portion of Silvestrini's superior engaging surface is used to guide a knife about the cornea. Since the disclosed shape of the superior engaging surface is circular, the cut is also circular. Nevertheless, Kawesch teaches the use of a holding device 30 that is oval (Col. 3, lines 1-10) and is used to cut an oval shape in the cornea. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Silvestrini tool guide (the superior engagement surface) to be oval as taught by Kawesch, in order to form an oval shaped cut into the cornea.

Claims 11, 12, and 16 are rejected under 35 U.S.C. 103(c) as being unpatentable over Silvestrini in view of Amano (US 6,506,198). Silvestrini discloses a kit to be used with a microkeratome having a cutting head assembly 100 (Fig. 1). The other limitations are explained in claim set 1. However, Silvestrini fails to disclose a plurality of rings having a different inferior engagement surface diameter from one another. Nevertheless, Amano teaches, "if the diameter of the flap should be made large or small, an appropriate one is selected from plural suction rings having respective, different opening diameters..." (Col. 1, lines 50-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a plurality of rings as taught by Amano such that a variety of inferior engagement surface ring diameters may be chosen from to make cuts of different sizes.

Claims 17 and 18 are rejected under 35 U.S.C. 103(c) as being unpatentable over Silvestrini in view of Amano and in further view of Kawesch. Silvestrini and Amano fail to disclose the superior engaging surface having a non-circular plane section and an oval shape. Nevertheless, Kawesch teaches the use of a holding device 30 that is oval (Col. 3, lines 1-10) and is used to cut an oval shape in the cornea. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Silvestrini/Amano tool guide, which is the superior engagement surface, to be oval as taught by Kawesch, in order to form an oval shaped cut into the cornea.

Claims 21-26 and 29-31 are rejected under 35 U.S.C. 103(c) as being unpatentable over Silvestrini in view of Carriazo (US 5,980,543). Silvestrini discloses a ring as disclosed in Figs. 9-11 having an aperture at the inferior engaging surface 514. He fails to disclose a cutting head, an adjustable cornea cutting device, and a means for driving. Nevertheless, Carriazo discloses a cutting head 30 to control the blade, an adjustable cornea compression device 50 to adjust the blade, and a drive means 20 to actuate the blade. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further include a cutting head to control the blade, an adjustable cornea compression device 50 to adjust the blade, and a drive means 20 to actuate the blade as taught by Carriazo. The cutting path is horizontal. The limitations of the dependent claims are met as set forth in claim set 1.

Claims 27 and 28 are rejected under 35 U.S.C. 103(c) as being unpatentable over Silvestrini in view of Carriazo and in further view of Kawesch. Silvestrini fails to disclose that the inferior engaging surface may be oval. Nevertheless, Kawesch teaches the use of a holding device 30 that is oval (Col. 3, lines 1-10) and is used to cut an oval shape in the cornea. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Silvestrini/Amano tool guide (the superior engagement surface) to be oval as taught by Kawesch, in order to form an oval shaped cut into the cornea.

Claim 32 is rejected under 35 U.S.C. 103(c) as being unpatentable over Silvestrini in view of Carriazo and in further view of Carriazo (US 6,296,650). Both Silvestrini and Carriazo '543 fail to disclose a pendular cutting path. Nevertheless, Carrizo '650 teaches a pendular cutting path (Fig. 1) to create a horizontal hinge, which will experience less ablation and traumatic displacement following surgery (Col. 9, lines 17-25).

### ***Response to Arguments***

Applicants' arguments submitted on June 18, 2003 regarding the drawing objection and the rejections under 35 U.S.C. 112, first paragraph, are considered persuasive and have been withdrawn. Applicants added the phrase, "microkeratomes having pendular as well as horizontal cutting paths," in order to overcome the "third deficiency," requiring that the limitation of claim 21, "the cutting path may be horizontal or pendular," be cited in the specification. This amendment to the specification does not overcome the rejection wherein a "driving means" was cited without sufficient disclosure in the specification to determine the metes and bounds of the claim. Nevertheless, sufficient disclosure is found in U.S. Pat. No. 5,980,543, which applicants incorporate by reference into the specification.

The arguments under to the rejections under 35 U.S.C. 102 and 103 are now moot in view of the new grounds of rejection.

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**Conclusion**

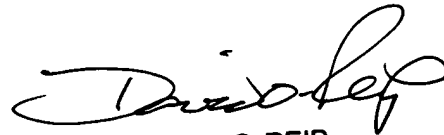
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



DJD  
July 23, 2003



DAVID O. REIP  
PRIMARY EXAMINER